K101264

510(k) Summary of Safety and Effectiveness

Submitter Information
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MAY 11 2010

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Date Prepared: 14 April 2010

Device Name
Common Name: Portable Patient Monitor
Proprietary Name: Tempus IC™ Professional Patient Monitor
Classification Name: Monitor, physiological, patient (without arrhythmia detection or alarms)

Device Description
The Tempus IC Professional is a multi-parameter vital signs monitor designed for use in pre-hospital care and remote clinical locations by trained healthcare professionals e.g. nurse, EMT, paramedic, physician, army corpsman etc. It provides 3 lead ECG monitoring, 12 lead ECG recording, pulse Oximetry, non-invasive blood pressure, sidestream Capnometry, a tympanic thermometer and user configurable alarms.

In addition, it provides the ability to transmit all vital signs data via wired or wireless Ethernet connections to a software system (called i2i) expected to be based in a facility far from the user e.g. a response centre facility. In addition to sending all vital signs, the system can also send pictures via an integrated camera, geographic position by an integrated GPS receiver and voice via a wired or wireless headset.

The device is intended to be used primarily as a standalone monitor for traditional monitoring applications. It is expected that its real-time telemedicine capabilities will be used in a minority of applications. When its telemedicine features are used it is intended that this will be for the purpose of obtaining support in the diagnosis and treatment decisions for the patient e.g. where the patient is in a remote country and the user's organisation needs to make an extraction or repatriation decision.

It is expected that the ability to transmit data in real-time will be performed in remote locations typically using satellite or terrestrial communications systems.

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The Tempus IC Professional is used in conjunction with i2i software, which provides a system for receiving real-time voice and vital signs data. The system enables users to receive voice, vital signs data, and still video pictures from Tempus IC Professional devices located anywhere in the world.

The i2i system can be used by commercial response centre service providers or by individuals or organisations wishing to provide their own internal service

I2i also supports a full patient records database.

Intended Use / Indications for Use
The Tempus IC Professional is a portable vital signs monitor intended to be used by clinicians and medically qualified personnel for the attended or unattended monitoring of single or multiple vital signs in clinical and pre-hospital care applications. The device is indicated for 3 Lead ECG monitoring and 12 Lead ECG recording, non-invasive blood pressure (NIBP), respiration, end-tidal CO2 ($ETCO_2$), pulse oximetry (SpO_2) and tympanic temperature.

The monitor is intended to be used as a stand-alone monitor or as a telemedicine system (transmitting patient data to other medical professionals located elsewhere).

The ECG Harness of the Tempus IC Professional is suitable for use on adults or children (over 10 years old and over 20kg in weight).

Predicate Devices
The Tempus IC Professional Patient Monitor is predicated on our existing model, the Tempus IC Patient Monitor, which was the subject of a previous submissions (K082718), and is being cited as the predicate for this new finished device (in addition to other predicates most notably the Propaq 102 which was cleared under K921497, K914838, K910882 and K910772).

The Tempus IC Professional Patient Monitor is the same hardware as the predicate (excepting a revised membrane keypad and offering the overmould in black as well as orange) but differs in terms of its intended use (intended for regular use by trained healthcare professionals) and the provision of ECG monitoring and user configurable alarms.

In addition, the Propaq 102 series patient monitor is cited as a predicate (K921497, K914838, K910882 and K910772) to demonstrate substantial equivalence of the Tempus IC Professional as a vital signs monitor for use by trained healthcare professionals – this predicate is being used as the predicate Tempus IC was not intended for this user group. The Propaq is a similar size, provides similar functions (3 lead ECG monitoring, SpO2, ETCO2, NIBP), provides monitoring and alarming functions and is intended for use in the same environments (clinic and emergency use) by the same personnel (trained healthcare professionals) for the same patients (adults and children).

Lastly, the Radiant Innovations TH809 thermometer is cited as a predicate (K011059) for the modified version (that provides Bluetooth communications of the measured readings) that will be provided with the Tempus IC Professional. The TH809 is a similar size and weight and is

the same in all respects except for the addition of a Bluetooth radio module which enables the measurement it reads to be transmitted to a Tempus IC Professional patient monitor.

Testing

The Tempus IC Professional uses currently available (OEM) technology found in many legally marketed devices.

Area	Testing Performed
ECG monitoring	Testing to AAMI EC13 has been performed.
EMC	The modified thermometer has been tested to IEC60601-1-2.
Alarms	The alarm functions of the product have been tested to IEC60601-1-8.
Biocompatibility	The ECG cables have been tested to ISO 10993-5 and ISO10993-10.
Comparative testing to predicates	Comparative testing has been performed to demonstrate that the performance of the device is equivalent to the predicates. This comprised benchmarking against the Propaq for ECG and alarm performance and against the TH809 for temperature measurement performance.
Software	The requirements of the FDA document *Guidance for the Content of Premarket Submissions for Software in Pre-Market Submissions* has been applied. In addition, the requirements of IEC62366 and IEC60601-1-4 have been addressed.
Bench testing	The product has been bench tested to confirm that transmitted data is transmitted reliably and accurately.
Wireless range	The thermometer has been tested to confirm it operates reliably and accurately at its maximum stated range.
Wireless co-existence testing	The thermometer has been tested to confirm it operates reliably in the presence of other wireless fields as per the FDA Guidance for Radio-Frequency Wireless Technology in Medical Devices.
Usability	Usability has been address by the application of IEC62366

Evidence of Conformity to Essential Principles

The device has been shown to conform to the essential principles for safety and performance defined in guidance prepared by the Global Harmonization Task Force Study Group1 (GHTF/SG1/N14R9:2005), with supporting evidence prepared in the summary technical documentation (STED) format recommended in final version of GHTF guidance (SG1/N011: 2008).

Specifically, this evidence includes performance testing, software validation, electrical safety, electromagnetic compatibility, and risk analysis, where third party testing has been conducted, if appropriate.

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The design of this device utilises currently available (OEM) technology found in many legally marketed devices. In terms of measurement performance, the Tempus IC Professional is effectively identical to the devices that incorporate the same OEM technology.

Conclusion

On the basis of these results and the above referenced testing, it is our determination that the device is safe, effective and performs as well as the legally marketed predicate device(s).

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Respectfully

Chris Hannan
Regulatory Affairs and Operations Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 11 2010

Remote Diagnostic Technologies Limited
c/o Mr. Daniel W. Lehtonen
Intertek Testing Services, NA, Inc.
Responsible Third Party Official
2307 E. Aurora Rd., Unit B7
Twinsburg, OH 44087

Re: K101264
Trade/Device Name: Tempus IC Professional Patient Monitor
Regulatory Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: May 3, 2010
Received: May 4, 2010

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): ~~Not known~~ K101264

Device Name: TempusIC™ Professional Patient Monitor

Indications for Use:

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Prescription Use: YES (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use: NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K101264